

Remarks

The January 21, 2009 Official Action has been carefully reviewed. In view of the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set forth in the January 21, 2009 Official Action. Therefore, the initial due date for response is April 21, 2009.

As another preliminary matter, Applicants note that the Examiner has listed claim 25 as "withdrawn" on the Official Action Summary. However, claim 25 is part of the elected invention and was examined on the merits in the past two Official Actions. Applicants respectfully request the Examiner correct this error and consider claim 25 on the merits.

Claim 33 has been rejected for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph on two grounds.

Claims 1-4, 9, 13, and 17-20 have been rejected under 35 U.S.C. §102(b) for allegedly being anticipated by WO 99/36050.

The Examiner has also rejected claims 9 and 29 under 35 U.S.C. §103(a) as allegedly unpatentable over WO 99/36050.

Lastly, claims 1-4, 9, 13, 17-20, 29, and 33 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over WO 99/04752 and Kunitz (J. Gen. Physiol. (1946) 29:149-154).

The foregoing rejections constitute all of the grounds set forth in the January 21, 2009 Official Action for refusing the present application.

In accordance with the instant amendment, Applicants have amended claim 1 by adding the features previously recited in claim 33. No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the 35 U.S.C. §112, first paragraph rejections of claim 33; the 35 U.S.C. §102(b) rejection of claims 1-4, 9, 13, and 17-20; and the 35 U.S.C. §103(a) rejections of claims 1-4, 9, 13, 17-20, 29, and 33, as set forth in the January 21, 2009 Official Action, cannot be maintained. These grounds of rejection are, therefore, respectfully traversed.

**CLAIM 33 SATISFIES THE WRITTEN DESCRIPTION REQUIREMENT OF 35
U.S.C. §112, FIRST PARAGRAPH**

Claim 33 has been rejected for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph on two grounds. First, the Examiner contends that the specification does not adequately support a "Kunitz-type" soybean trypsin inhibitor. Second, the Examiner alleges that "the specification does not provide a reasonably representative disclosure of useful non-denatured, Kunitz-type soybean trypsin inhibitors, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions." Applicants respectfully disagree with the Examiner's position for the reason set forth below.

At the outset, Applicants have cancelled claim 33 and have amended claim 1 to recite the features previously recited in claim 33.

With regard to the new matter rejection, Applicants respectfully submit that there is clear support for the term "Kunitz-type" inhibitor in the instant specification. It is a well established principle of patent law that "to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention" (MPEP at §2163(I)). Information which is well known in the art need not be described in detail in the specification (MPEP at §2163(II) (A) (2)). Hybritech, Inc. v. Monoclonal Antibodies,

Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). Moreover, "patents are written to enable those skilled in the art to practice the invention. A patent need not disclose what is well known in the art." In re Wands, 858 F.2d 731, USPQ2d 1400, 1402 (Fed. Cir. 1988). The Federal Circuit has further explained that:

The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. To hold otherwise would require every patent document to include a technical treatise for the unskilled reader. Although an accommodation to the "common experience" of lay persons may be feasible, it is an unnecessary burden for inventors and has long been rejected as a requirement of patent disclosures. S3, Inc. v. Nvidia Corp., 259 F.3d 1364, 1371, 59 USPQ2d 1745, 1749-50 (Fed. Cir. 2001).

Moreover, the Supreme Court stated in Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437-38, 22 S. Ct. 698, 711-12, 46 L. Ed. 968 (1902) that:

The specification of the patent is not addressed to lawyers, or even to the public generally, but to the manufacturers of steel; and **any description which is sufficient to apprise them in the language of the art of the definite feature of the invention, and to serve as a warning to others of what the patent claims as a monopoly, is sufficiently definite to sustain the patent.** He may assume that what was already known in the art of manufacturing steel was known to them, and, as observed by Mr. Justice Bradley in Webster Loom Co. v. Higgins, 105 U. S. 580, 586, 26 L. Ed. 1177, 1179, 'he may begin at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.' [Emphasis added.]

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

Indeed, "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient" (MPEP at §2163(II) (A) (3) (a)). Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

Soybean trypsin inhibitor (STI) is a different inhibitor than the Bowman-Birk protease inhibitor (BBI; see, for example, page 4, lines 17-26). Indeed, STI is a more heat labile inhibitor than BBI (see page 4, lines 22-26). The GenBank Accession No. provided at page 26, line 17, as an example of an STI, is described as a Kunitz trypsin inhibitor (see AF314823 submitted herewith). Notably, GenBank Accession No. AF314823 was incorporated by reference (see page 7, lines 7-9). Thus, the specification provides clear support for a Kunitz type soybean trypsin inhibitor.

Applicants also submit that, as of the effective filing date of the instant application, it was well known in the art that soybean trypsin inhibitor (STI) was a pseudonym for Kunitz-type soybean trypsin inhibitor. In support of this position, Applicants submit several references and abstracts which demonstrate the equivalency of the terms STI and Kunitz-type soybean trypsin inhibitor (see, e.g., Birk (Arch. Latinoam. Nutr. (1996) 44(4 Suppl 1):26S-30S); Gladysheva et al. (Biochemistry (Mosc.) (1999) 64:1244-1249); Song and Suh (J. Mol. Biol. (1998) 275:347-363); De Meester et al. (Acta Crystallogr. D. Biol. Crystallogr. (1998) 54:589-597); Takahara et al. (J. Biol. Chem. (1985) 260:8378-8383); and Dattagupta et al. (Acta Crystallogr. D. Biol. Crystallogr. (1996) 52:521-528)). Each of these references pre-dates the effective filing date of the instant application. Gladysheva et al. (Biochemistry (Mosc) (1999) 64(11):1244-9) teach that BBI is capable of binding trypsin, chymotrypsin, and chymotrypsin-like proteases whereas STI is a trypsin inhibitor (see, for example, page 1244). Gladysheva et al. also expressly state "Bowman-Birk (BBI) and Kunitz (STI) type inhibitors from soybean was investigated," thereby indicating that STIs are Kunitz type inhibitors (see abstract). Indeed,

each of the above cited abstracts equates Kunitz with STI. Moreover, the abstracts of De Meester et al. and Song and Suh specifically recite Kunitz-type soybean trypsin inhibitors as STIs. Thus, it is clear that, as of the effective filing date of the instant application, a skilled artisan would appreciate that STI and Kunitz-type soybean trypsin inhibitor are synonymous and interchangeable terms.

With regard to the written description rejection, the Examiner contends at page 3 of the instant Official Action that "mere indistinct terms (such as "non-denatured, Kunitz-type soybean trypsin inhibitors" used herein), however, may not suffice to meet the written description requirement."

Applicants respectfully disagree. As stated hereinabove, "to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention" (MPEP at §2163(I)). The phrase "non-denatured, Kunitz-type soybean trypsin inhibitor" is clearly not a "mere indistinct term," as asserted by the Examiner. The phrase clearly refers to Kunitz trypsin inhibitors isolated from soybean. Further, Kunitz type inhibitors are a well-defined family of trypsin inhibitors. Indeed, Applicants provide herewith Kunitz (J. Gen. Physiol. (1947) 30:311-320) which describes the soybean Kunitz trypsin inhibitor, thereby demonstrating that this inhibitor was known for at least 50 years prior to the earliest filing date of the instant application. Kunitz type trypsin inhibitors have been very well characterized over the years such that a skilled artisan would be well apprised of the trypsin inhibitors encompassed by the term and would understand that the instant inventors were in possession of the claimed invention. Nothing more is needed to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

As further evidence, Applicants also submit herewith Mukhopadhyay (J. Mol. Evol. (2000) 50:214-223) and U.S. Patent

6,689,582, which were cited in the parent application (U.S. Patent Application No. 10/108,248). Column 3, line 36 through column 4, line 59 of the '582 patent generally describes and characterizes Kunitz inhibitors. Further, the '582 patent discusses Kunitz-type soybean trypsin inhibitors, as opposed to Kunitz inhibitors in general, at column 4, lines 48-59, and states that "soybean trypsin inhibitor (STI) is a potent Kunitz family inhibitor of trypsin."

Mukhopadhyay generally discusses protease inhibitors. At Table 1, Mukhopadhyay refers to a "Kunitz-STI family" of inhibitors (see also the phylogenetic trees in Figures 1A and 1B). This "Kunitz-STI family" of inhibitors includes two Kunitz-type winged bean protease inhibitors (ICW3_PSOTE, ALB1-PSOTE), a Kunitz-type coral tree protease inhibitor (IDE3_ERYCA), a Kunitz-type giant taro protease inhibitor (ITC_ALOMA), a Kunitz-type papaya protease inhibitor (LSPI_CARPA), a Kunitz-type potato trypsin inhibitor (PXIK_SOLTU), a Kunitz-type poplar tree trypsin inhibitor, and one Kunitz-type soybean trypsin inhibitor (KTI1_SOYBN). Notably, the amino acid sequence of the Kunitz-type soybean trypsin inhibitor is highly homologous to the amino acid sequence provided in GenBank Accession No. AF314823 (cited in the instant application).

It is clear from the above that Applicants described the use of any Kunitz-type soybean trypsin inhibitor in the methods of the instant invention. The application provides an exemplary inhibitor: GenBank Accession No. AF314823 and the parent application (10/108,248), which is incorporated by reference into the instant application also provides another Kunitz-type soybean trypsin inhibitor example: Sigma product number T9003 (see Table 1). Furthermore, the references provided herewith characterize Kunitz inhibitors in general and describe Kunitz-type soybean trypsin inhibitors as a member of Kunitz family of inhibitors. This smaller genus of Kunitz-type soybean trypsin inhibitors is fully supported by the disclosure of the two Kunitz-type soybean trypsin

inhibitors and the high degree of homology present among Kunitz-type soybean trypsin inhibitors.

In view of all of the foregoing, Applicants submit that the rejections of claim 33 under 35 U.S.C. §112, first paragraph cannot be reasonably maintained. Indeed, it is without question that the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Withdrawal of the rejections is respectfully requested.

CLAIMS 1-4, 13, AND 17-20 ARE NOT ANTICIPATED BY WO 99/36050

Claims 1-4, 13, and 17-20 have been rejected under 35 U.S.C §102(b) for allegedly being anticipated by WO 99/36050. The '050 application allegedly discloses using soy extracts for protecting skin from UV damage. It is also the Examiner's position that the soy extract is non-denatured because the soy beans are extracted without using enzymes or temperature. Applicants respectfully disagree with the Examiner's position for the reasons of record and those set forth below.

As stated in the October 24, 2008 Official Action response, the '050 application clearly states at page 11, lines 23-24 that "extracts of soy or clover may be prepared according to WO 93/23069" and Example 1 of the '050 application also clearly indicates that the extracts were prepared according to the methods of WO 93/23069. Significantly, the processes for preparing soy products described by the '069 application involve heating the plant product.

At page 5 of the instant Official Action, the Examiner states that "turning to '069 as Applicants suggest, Examiner finds Applicants mischaracterized the disclosure where in Example 1, the first step of drying the raw plant may be accomplished either by sun-drying or from applied heat." However, Example 1 of the '069 application is clearly drawn to

the preparation of red clover product. In stark contrast, the instantly claimed methods are drawn to soybean products. Example 2 of the '069 application is drawn to methods of preparing soybean products. Significantly, the first step in the process of preparing a soy product according to the '069 application, is heating in dry air (see page 18, line 25). Accordingly, the methods of the '069 application require heat denaturation for the preparation of a soy product. Inasmuch as the '050 application states that soy extracts were prepared in accordance with the methods of the '069 application and the '069 application clearly states that the soy was heated, one is left with the inescapable conclusion that the '050 application used heat-denatured soybean, in complete contrast to the instantly claimed invention.

As stated in the October 24, 2008 Official Action response, it is also noteworthy that the '050 application and the '069 application are concerned with using the isoflavone compounds and phyto-oestrogen compounds (which include isoflavones), respectively, contained within soy or clover (see Abstract and claims). Isoflavones are not proteins, but rather are small chemical compounds which are well-known to be resistant to heat which denatures proteins. Accordingly, a skilled artisan, apprised of the '050 and '069 applications, would not have any motivation in omitting the heating steps described in the purification methods in these applications.

Applicants have also amended claim 1 to recite the features previously recited in claim 33, which was not included in the instant rejection. Indeed, the references cited by the Examiner fail to teach or suggest the features recited in claim 33.

In view of all of the foregoing, it is evident that the rejection of claims 1-4, 13, and 17-20 under 35 U.S.C §102(b) is untenable. Withdrawal of the rejection is respectfully requested.

CLAIMS 9 AND 29 ARE NOT RENDERED OBVIOUS BY WO 99/36050

The Examiner has rejected claims 9 and 29 under 35 U.S.C §103(a) as allegedly unpatentable over WO 99/36050. The Examiner states that the '050 application "does not disclose the instant emulsifier range from about 0.1 to about 20%." However, it is the Examiner's position that it would have been obvious to a skilled artisan to use an emulsifier in the claimed range. Applicants continue to respectfully disagree with the Examiner's position for the reasons of record and those set forth herein.

As stated hereinabove, the '050 application, as evidenced by the '069 application, only teach or suggest the use of a heat denatured soy product. Inasmuch as the purification/extraction methods described in the '050 and '069 applications include heat denaturation, it is evident that the '050 application fails to teach or suggest the use of a non-denatured soy product as instantly claimed.

Applicants have also amended claim 1 to recite the features previously recited in claim 33, which was not included in the instant rejection. Indeed, the references cited by the Examiner fail to teach or suggest the features recited in claim 33.

In view of the foregoing, it is clear that the instant rejection of claims 9 and 29 under 35 U.S.C §103(a) is untenable. Withdrawal of the rejection is respectfully requested.

CLAIMS 1-4, 9, 13, 17-20, 29, AND 33 ARE NOT RENDERED

OBVIOUS BY WO 99/04752 IN VIEW OF KUNITZ

Claims 1-4, 9, 13, 17-20, 29, and 33 have been rejected under 35 U.S.C §103(a) as allegedly unpatentable over the '752 application and Kunitz. The '752 application allegedly discloses the application of a soybean trypsin inhibitor. The Examiner contends that while the '752 application does not specifically teach the administration of a non-denatured Kunitz-type soybean trypsin inhibitor, it

would have been obvious to use such an inhibitor in view of Kunitz.

Applicants respectfully disagree with the Examiner's position. The '752 application describes methods and compositions for bringing about changes in skin pigmentation and affect melanogenesis. In stark contrast, the instant claims recite methods of "reducing the risk of cutaneous tumor development in skin cells." The '752 application wholly fails to teach or suggest that the administration of a non-denatured soy product would have any benefit in reducing the risk of cutaneous tumor development. Kunitz also fails to teach or suggest any anti-tumor property for a non-denatured soy product.

Furthermore, the instant claims recite "reducing the risk of cutaneous tumor development in skin cells **that have not yet been damaged by ultraviolet radiation**" (emphasis added). Indeed, the instant specification states at page 1, lines 27-30 that "UVB ... is the main cause of sunburn, tanning, aging of the skin, and skin cancer." The instant specification demonstrates that the application of a composition comprising non-denatured soy product prior to damaging UVB exposure reduces UVB damage to cells and reduces the risk to skin cancer. In stark contrast, the '752 application describes soybean trypsin inhibitor as depigmenting agent (see, e.g., Examples 11-14). Accordingly, the '752 application calls for the application of the soybean trypsin inhibitor **after** the skin has been exposed to UVB (i.e., tanned or damaged (e.g., age spots (see Example 13 of the '752 application))). In view of the foregoing, it is evident that the '752 application, in fact, teaches away from the instantly claimed methods.

Applicants also submit that, as stated in §2111.02 of the MPEP, a "claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble,

when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Moreover, the MPEP at §2111.02(II) states that "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963)." Here, the recitation in the preamble of a "method of reducing the risk of cutaneous tumor development in skin cells" results in a manipulative difference between the claimed invention and the prior art.

In view of all of the foregoing, Applicants submit that the rejection of claims 1-4, 9, 13, 17-20, 29, and 33 under 35 U.S.C §103(a) cannot be reasonable maintained. Withdrawal of the rejection is respectfully requested.

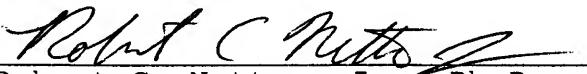
CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the foregoing remarks, it is respectfully urged that the rejections set forth in the January 21, 2009 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
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Enclosures: GenBank Accession No. AF314823
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1):26S-30S (Abstract only)
Gladysheva et al., Biochemistry (Mosc.) (1999)
64:1244-1249
Song and Suh, J. Mol. Biol. (1998) 275:347-363
(Abstract only)
De Meester et al., Acta Crystallogr. D. Biol.
Crystallogr. (1998) 54:589-597 (Abstract only)
Takahara et al. (J. Biol. Chem. (1985) 260:8378-
8383 (Abstract only)
Dattagupta et al., Acta Crystallogr. D. Biol.
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Kunitz, J. Gen. Physiol. (1947) 30:311-320
Mukhopadhyay, J. Mol. Evol. (2000) 50:214-223